REMARKS/ARGUMENTS

Claims 75, 77, 84-89 and 91 are pending. By way of the present amendment, four (4) claims have been amended. Applicant respectfully submits that no new matter has been added by way of this amendment. Illustrative support in the specification can be found at least at page 35:11-20; page 36:10-20; page 44:10-30; page 45:10-47:20.

I. THE REJECTION UNDER 35 U.S.C. § 112 SHOULD BE WITHDRAWN.

The Office Action rejected claims 75, 77, 84-89 and 91 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement because of the limitation "in an amount more than about 20 times the amount of the omeprazole on a weight to weight basis in the composition".

Applicant respectfully disagrees with the Office Action's assertion its previous response failed to provide any calculation showing how the range is determined. Indeed, as the claims are drafted in the context of a solid pharmaceutical tablet for oral administration, one of skill in the art would appreciate that "an amount more than about 20 times the amount of the omeprazole on a weight to weight basis in the composition" must be a practically feasible amount. In any event, for the sake of expediting prosecution, the presently pending claims describe the amount of buffering agent in terms of a range relative to the amount of omeprazole used in the claimed formulation, *i.e.*, about 10 to 40 mg of omeprazole.

The range values present in the pending claims are easily recited by the specification including the formulations described therein, as demonstrated below. The issue of written description is not whether these claimed limitations are explicitly in the specification, but instead "whether one of skill in the art could derive the claimed ranges from the … disclosure." *Union Oil Co. of Cal. v. Atlantic Richfield Co.*, 208 F.3d 989, 54 USPQ.2d 1227 (Fed. Cir. 2000). Applicant has plainly demonstrated that this is the case.

Here, the specification expressly discloses tablets comprising about 1 mEq to about 20 mEq of sodium bicarbonate. *See* page 35, lines 11-13. In addition, since the portions of the priority document cited by Examiner in fact provides written description supports the claimed composition, it is not available as prior art. For example, formulations B, C and D of the priority document, cited on page 5 of the office action, discloses buffer comprising 250 mg sodium bicarbonate for a 10 mg tablet of omeprazole, 250 mg of sodium bicarbonate for a 20 mg tablet

of omeprazole and 500 mg of buffer for a 20 mg tablet of omeprazole, respectively. These identical disclosures are in the application as filed at pages 45:12-46:20.

Indeed, the specification further discloses two additional tablet formulations with about 250 mg of sodium bicarbonate and 400 mg of sodium bicarbonate, each in tablet formulations comrpising 10 mg of omeprazole. *See, e.g.*, formulation F and G at 47:1-21. In addition, the specification discloses different a tablet formulations comprising 975 mg of sodium bicarbonate for tablets comprising 20 mg of omeprazole, which falls within the claimed range of about 1 mEq to about 20 mEq of omeprazole. *See, e.g.*, 47:23-48: 27.

Accordingly, the present claims have written description support in the application as filed and all priority documents, including U.S. Patent No. 6,489,346 ("Phillips"). Therefore, in view of the present amendments and foregoing amendments remarks, Applicant respectfully submits that the rejection under 35 U.S.C. § 112, first paragraph, and should be withdrawn.

II. THE REJECTION UNDER 35 U.S.C. § 102 SHOULD BE WITHDRAWN.

The Office Action dated March 31, 2011 rejected claims 75, 77, 84-86, 88 and 91 under 102(b) based on U.S. Patent No. 6,489,346 ("Phillips"). As discussed in Section I, above, no new matter has been added to the present specification, and support can be found throughout the priority documents.

In addition, the Office Action acknowledges that the same portions of U.S. Patent No. 6,489,346 as being allegedly anticipatory in fact provide written description support for the claimed formulations. Therefore, there is no new matter introduced by way of this or any previously filed preliminary amendments. Indeed, the instant application is a continuation of prior application no. 10/407,552, which is a continuation of application no. 10/260,132, filed Sept. 30, 2002, which is a continuation of application no. 09/481,207, filed on Jan. 11, 2000, which issued as U.S. Patent No. 6,489,346. U.S. Patent No. 6,489,346 is not available as a 102(b) reference, and Applicant respectfully requests that the rejection under 102(b) be withdrawn in light of the current amendments and remarks.

III. THE REJECTION UNDER 35 U.S.C. § 103 SHOULD BE WITHDRAWN.

Claims 75, 77, 84-89 and 91 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over US 5,447,918 ("McCullough") in view of Carroll, EP 584,588 ("Nomura") or US 6,268,385 ("Whittle"). Applicant respectfully traverses this rejection, since no combination

of the references cited disclose every feature of the pending amended claims. Further, there is no apparent reason to combine the references in the manner suggest by the examiner nor a reasonable expectation of success thereof.

The references cited in the Office Action dated March 31, 2011, alone or in combination, fail to teach all limitations of the claims as presently amended. The office action fails to cite any apparent reason why one of skill in the art would apply the teachings of McCullough to the cited art to develop a non-enteric tablet formulation comprising about 10-40 mg of omeprazole, about 1 mEq to about 20 mEq of sodium bicarbonate and a disintegrant. McCullough's teachings focus on compositions requiring the use of sucralfate. By contrast, the present invention teaches away from using sucralfate as the active ingredient. *See, e.g.*, 8:3-18, 15:19-22, 22:27-31, 51:5-10. In fact, although McCullough attempts to make various combinations with various acid-related active ingredients, the cited portions of McCullough (Columns 15-16, example 12) never teach the use of a tablet comprising non-enteric coated omeprazole and sodium bicarbonate in the ranges claimed together with a disintegrant. There is no apparent teaching to employ acid-labile active agents with the embodiments touted by McCullough.

Likewise, Carroll and Whittle fail to render the pending claims obvious. Carroll fails to teach a tablet formulation of non-enteric coated omeprazole, and Whittle does not teach the use of a non-enteric coated proton pump inhibitor in a tablet dosage form, let alone non-enteric coated omeprazole with sodium bicarbonate in the claimed ranges. The office action cites nothing in Carroll or Whittle that would suggest to the skilled artisan to combine their teachings with Nomura. In fact, Nomura makes no disclosure of tablet formulations containing the claimed amounts of sodium bicarbonate and non-enteric coated omeprazole in a tablet. Further, the cases cited by the examiner are inapposite to the extent that they are relied upon by the March 31st office action for factual support as to how the person of skill in the art in the claimed invention would view the present invention, which is directed to gastric-acid related pharmaceutical compositions.

Based on the foregoing reasons and amendments, a *prima facie* case of obviousness has not been established. Accordingly, amended claims 75, 77, 84-89 and 91 are not obvious over the cited references. Therefore, Applicant respectfully requests withdrawal of this rejection.

IV. PROVISIONAL OBVIOUSNESS-TYPE DOUBLE PATENTING

Claims 75, 77, 84-89 and 91 have been provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over various claims of co-pending Application Nos. 10/407,522 and 10/418,410. In addition, Claims 75, 77, 84-89 and 91 have been rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over several claims of U.S. Patent Nos. 6,780,882, 6,699,885 and 7,399,772. Applicant will submit a terminal disclaimer once allowable subject matter is indicated.

CONCLUSION

For at least the foregoing reasons, it is respectfully submitted that the claims as submitted by way of this amendment are in condition for allowance. Early and favorable consideration is respectfully requested, and the Examiner is encouraged to contact the undersigned with any questions or to otherwise expedite prosecution. Further, none of Applicant's amendments or cancellations are to be construed as dedicating any such subject matter to the public, and Applicant reserves all rights to pursue any such subject matter in this or a related patent application.

Kindly contact the undersigned with any questions or to otherwise expedite prosecution.

Respectfully submitted,

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